REMARKS

Claims 1-3 and 5-20 are pending, claims 5, 8-12 and 15-20 are withdrawn.

Claims 1, 3, 4, 5, 13 and 14 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Okada et al. (US 6,455,053). Claims 1, 3, 13 and 14 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by DuRoss (US 5,075,291). Claims 1-3, 6, 7, 13 and 14 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Okada et al. Claims 1-3, 13 and 14 were rejected under 35 U.S.C. §103(a) as allegedly obvious over DuRoss in view of Okada et al.

Claim 14 was objected to as being substantial duplicate of claim 13 and claim 6 was objected to as containing misspelling. By this Amendment, Applicant amends claims 6 and 14 to correct minor typographical errors. Support for amendment to claims 6 and 14 may be found in the specification and claims as originally filed. No new matter has been added.

Applicants respectfully request reconsideration and allowance of all pending claims in view of the amendment to the claims and the remarks set forth below.

I. Anticipation Rejection Over Okada et al.

The Examiner maintained the rejection of claims 1, 3, 4, 5, 13 and 14[1] as anticipated by Okada et al. It appears to be the Examiner's view that even though the process of Okada et al. is different, the product of Okada et al. and the invention are identical. The Examiner then cites *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) for the proposition that ""[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. ... If the product in the product-by-process claims in the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

[1] Applicants note that claim 4 has been previously cancelled and claim 6 stands withdrawn.

Applicants respectfully disagree.

In general, to anticipate a claim, a reference must disclose, either explicitly or inherently, each and every element of the claim. *Verdegaal Bros. v. Union Oil Co. of Cal.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). With respect to product-by-process claims, Applicants would like to direct Examiner's attention to the recent *en banc* decision of the Federal Circuit in *Abbott Labs v. Sandoz*, 566 F.3d 1282 (Fed. Cir. 2009), a copy of which is hereby attached as Exhibit 1. In *Abbott*, the Federal Circuit, *en banc,* held that the limitations of a product-by-process claim do limit the claim in determining both infringement and validity. The Federal Circuit reconciled older decisions which were in conflict on whether process elements limit product-by-process claims. *Id.* The Federal Circuit specifically overruled Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 1583 (Fed. Cir. 1991) and thus by clear inference the decision of *In re Thorpe* cited by the Examiner. Hence, now to establish anticipation of a product-by-process claim, the Examiner must show that the prior art discloses all of the claimed process limitations. *See Abbott Labs v. Sandoz*, 566 F.3d at 1293.

Claim 1 recites:

> 1. (Presently Amended) A drop pill comprising a pharmaceutical active ingredient and at least one pharmaceutically acceptable matrix adjuvants selected from a group consisting of D-ribose, fructose, glucose, xylose, trehalose, raffinose, maltose, gelose, sucrose ester, D-ribonic acid-γ-lactone; erythritol, sorbitol, xylitol, arabitol, isomaltitol, lactitol, malic acid, citric acid; said drop pill is prepared by **dripping** a solution, suspension, or emulsion of said pharmaceutical active ingredient with said at least one pharmaceutically acceptable matrix adjuvant **into a coolant. [emphasis added].**

Thus, claim 1 recites dripping a solution or suspension into a coolant. Okada et al. does not disclose this explicit limitation of claim 1. In fact, Okada et al. discloses a process wherein a mixture is charged into a mold, followed by air-drying. Okada et al. does not disclose every

element of claim 1, either explicitly or inherently as required under *Abbott*. See *Abbott* 566 F.3d at 1293.

In addition, the product claimed in the present application is in fact different from the product of Okada et al. Applicants hereby submit a Declaration by Dr. Chen Jianming ("the *Jianming Declaration*" Exhibit 2). The Examiner's attention is directed to paragraphs 9-11 of the *Jianming Declaration*. As shown, the product claimed in the present application is harder and has a significantly longer disintegration time than the product of Okada et al. Applicants assert that the structure and properties of the product of Okada is different than the drop pill of claim 1.

Withdrawal of the anticipation rejection of independent claim 1 and dependent claims, 3, 13 and 14 over Okada et al. is respectfully requested.

II. Anticipation Rejection Over DuRoss

The Examiner rejected claims 1, 3, 13 and 14 as anticipated by DuRoss. The Examiner states that DuRoss and the instant claims teach a process in which a solution is heated and then cooled. On this basis, the Examiner concludes that even though the process of DuRoss is different, the products of DuRoss and the invention are identical.

Applicants respectfully disagree.

Claim 1 of the present application recites dripping a solution suspension or emulsion into a coolant. DuRoss does not disclose this explicit limitation of claim 1. DuRoss discloses placing a melt, consisting of the pharmaceutical active ingredient and a sugar alcohol, on a tray to dry and slowly cooling until crystallized. DuRoss does not disclose a pill formed via dripping and therefore does not disclose "drop pill." Similarly, DuRoss does not disclose "dripping … into a coolant." Thus, DuRoss does not disclose every element of claim 1, either explicitly or inherently. Reference is made again to *Abbott*, *supra* at 1293.

In addition, the product claimed in the present application is in fact different from the

product of DuRoss. The Examiner's attention is directed to paragraphs 14 and 17 of the *Jianming Declaration* which includes evidence that the claimed invention yields a drop pill which is different than the product of DuRoss. As shown in the *Jianming Declaration*, the drop pills of the present application and DuRoss's product have different crystalline states. Further, the dissolution percentage of the drop pill as claimed in the '078 application is higher than that of the DuRoss product. In particular, after 2 minutes, the dissolution percentage of the product of DuRoss is 73.55% as compared to 94.60% dissolution percentage of the drop pill of the claimed invention. Applicants assert that the structure and properties of the drop pill as claimed is different than the product of DuRoss.

Withdrawal of the anticipation rejection of independent claim 1 and dependent claims 3, 13 and 14 over DuRoss is respectfully requested.

III. Obviousness Rejection Over Okada et al.

The Examiner maintained the rejection of claims 1-3, 6, 7, 13, 14 as allegedly obvious over Okada et al.

Applicants respectfully disagree and reference the previous section herein above.

To establish a *prima facie* case of obviousness, the Examiner must show that the prior art discloses, teaches or suggest each limitation of the claims at issue, MPEP §2143.03, or at least provides an "apparent reason" to modify the prior art in the direction of the claimed invention. The Examiner must further show that one skilled in the art would have a reasonable expectation of success to modify the prior art to arrive at the claimed invention.

As shown above, claim limitations 'drop pill" and "dripping ... into a coolant" are not found in Okada et al. Thus, Okada et al. alone or in combination, does not disclose, teach or suggest every limitation of the rejected claims. Hence, the Examiner has not established a *prima facie* case of obviousness.

Moreover, one skilled in the art would have no apparent reason to modify the teachings of Okada to arrive at the drop pill of the claimed invention.

The objective of Okada et al. is "to provide solid preparation which disintegrates and dissolves rapidly." See Okada et al., column 1, lines 66-67 to column 2, line 1. To achieve the rapidly dissolving product the Okada process requires, *inter alia*, removal of moisture or solvent from the mixture, and evaporation during formation of the solid. This results in many micro-pores being produced during the preparation. (*Jianming Declaration*, paragraph 10). As a result, the preparation disclosed by Okada et al. produces a product that is loose in structure with many micro-pores, capable of rapid dissolution.

In contrast, in the process claimed in the present application, no evaporation or sublimation occurs during the formation of a drop pill, and thus, no micro-pores are produced. This results in a drop pill that is denser and has a slower disintegration time. (See *Jianming Declaration.* paragraph 10).

Furthermore, Applicants surprisingly found advantages in some aspects over the rapidly dissolving preparation disclosed by Okada et al. As discussed above, the claimed drop pills of the present application are harder than the rapidly dissolving preparation disclosed by Okada et al. Thus making the drop pills of the present application are more resistant to pressure, are easier package, transport and store.

Withdrawal of the obviousness rejection of claims 1-3, 6, 7, 13 and 14 over Okada is respectfully requested.

IV. Obviousness Rejection Over DuRoss in view of Okada et al.

The Examiner rejected claims 1-3, 13 and 14 as being unpatentable over DuRoss in view of Okada et al., in that DuRoss discloses compositions comprised of sorbitol and a pharmaceutically active ingredient and Okada et al. discloses a variety of extracts from various plants. The Examiner concludes that it would have been obvious to prepare a pharmaceutical

composition as disclosed in DuRoss and use an extract of a crude drug as the active ingredient. The Examiner additionally states that both cited references and the claimed invention teach a process of making in which a solution is heated and then cooled. The Examiner thus concludes that the products produced are the same.

Applicants disagree.

As indicated above, the claim limitations "drop pill" and "dripping ... into a coolant" are not found in DuRoss or Okada et al. Thus, neither DuRoss or Okada et al., alone or in combination teach, disclose or suggest every limitation of the rejected claims. Hence, the Examiner has not established a *prima facie* case of obviousness.

Furthermore, one skilled in the art would have no "apparent reason" to modify the teachings of DuRoss in the direction of the claimed invention. DuRoss discloses placing a melt, consisting of the pharmaceutical active ingredient and a sugar alcohol, on a tray to dry and slowly cooling until crystallized. The product of DuRoss has to be further modified to provide a powder that can be make into tablets. Consequently, DuRoss does not provide a method for making a tablet or pill. Instead DuRoss discloses a process for the controlled crystallization of the melt. Hence, modification of the process of DuRoss with the teachings of Okada et al would not result in the formation of any tablet or pill let alone the drop pill as claimed in the present application. One skilled in the art would simply have no reasonable expectation of obtaining the drop pill of the rejected claims by modifying the process of DuRoss with the extract of Okada et al.

In addition, in developing the product of the claimed invention, applicants surprisingly found advantages in some aspects over the product of the cited art. As discussed above, the claimed drop pills of the present application are harder and have a slower disintegration time than the rapidly dissolving preparation disclosed by Okada et al. and have a dissolution percentage which is much higher than the product of DuRoss. Hence, the drop pills of the present application are more resistant to pressure, are easier package, transport and store than the product of the cited references.

In summary, Applicants respectfully submit that the cited references, alone or in combination, do not disclose, teach or suggest each and every limitation of claim 1, nor is there any apparent reason to modify the cited references in the direction of the claimed invention. One skilled in the art would simply have no reason to expect that modification of DuRoss process with the extract of Okada et al. would result in the drop pill of the rejected claims.

Applicants respectfully request reconsideration of claims 1-3, 13 and 14.

Claim Objections

Amendment of claims 6 and 14 makes this objection moot. Withdrawal of these objections is respectfully requested.

The Applicants therefore respectfully request reconsideration and allowance in view of the above remarks and amendments. The Examiner is authorized to deduct additional fees believed due from our Deposit Account No. 50-4711.

Respectfully submitted,

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